

### REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action Summary correctly indicates that claims 1-3, 5-12, 20, 22-41, 46-52 and 54-66 are pending in the application. Claims 1-3, 5-12, 20, 22-41, 46-52 and 54-66 stand rejected.

By the present amendment, claims 1, 26, 46-52 and 63 have been canceled without prejudice or disclaimer of the subject matter described therein. Claim 7 has been rewritten in independent form, incorporating the language of claim 1, and claims 2, 3, 5, 6, 8, 9, 20 and 22-25 have been amended to depend from claim 7 in view of the cancellation of claim 1. Claim 67 is added, reciting subject matter formerly recited in claim 58. Additional amendments of a formal nature have been made throughout the claims as described below.

No prohibited new matter has been introduced by way of the above amendments. Support for the claims as amended can be found throughout specification and original claims as previously described. Applicants reserve the right to file a continuation or divisional application on subject matter canceled by way of this Amendment.

### **Claim Objections**

Claims 5-8, 28-41, 46-52 and 54-66 have been objected to, allegedly because SEQ ID NOS: 1-6, recited therein, are DNA sequences and not amino acid sequences. No authority for the objection is stated. The objection is respectfully traversed, because one skilled in the art would clearly understand the subject matter described by the claims as presented. Claims 46-52 have been canceled, therefore the objection is moot with respect thereto.

As an example, Claim 5 recites “the nucleotide sequence encoding any of the amino acid sequences of SEQ ID NOS: 1 to 6.” It is noted that SEQ ID NOS: 1-6 explicitly describe both DNA sequences and the amino acid sequences encoded thereby. The CDS (coding sequence) feature of SEQ ID NO:1 is indicated in the Sequence Listing as corresponding to positions 6 to 1412 of SEQ ID NO: 1. The amino acid sequence encoded by the coding sequence of SEQ ID NO: 1 is shown in the sequence below the corresponding nucleic acid sequence. One skilled in the art would understand that “the amino acid sequence of SEQ ID NOS: 1-6” recited in claim 5 refers to the amino acid sequences encoded by SEQ ID NOS: 1-6 respectively as shown in the Sequence Listing. Likewise, one skilled in the art would understand the meaning of the “amino acid sequences as set forth in SEQ ID NOS: 1 to 6” recited, for example, in claim 28.

For at least the foregoing reasons, the subject matter of claims 5-8, 28-41 and 54-66 is particularly pointed out and distinctly claimed. Withdrawal of the objection is respectfully requested.

Claims 9, 25, 29, 33, 36, 55, and 62 have been objected to, allegedly because “a polynucleotide” should be “the polynucleotide.” Claims 10, 30 and 56 have been objected to, allegedly because “a vector” should be “the vector.” Without agreeing that such an amendment is necessary, but simply in order to expedite prosecution, claims 9, 10, 25, 29, 30, 33, 36, 55, 56 and 62 have been amended as suggested. Further, claims 11-12, 31-32 and 57-58 have been amended to replace the article “a” with “the” for consistency of usage where a previous claim is referenced. Withdrawal of the objections is respectfully requested.

Claims 25 and 62 have been objected to for reciting “tissues thereof.” Without agreeing that such an amendment was necessary, but simply in order to expedite prosecution,

claims 25 and 62 have been amended to replace "tissues thereof" with the equivalent "tissue of said plant or said progeny." Withdrawal of the objection is respectfully requested.

Claim 27 has been objected to for reciting "plants progeny." Claim 27 has been amended to include the possessive apostrophe. Withdrawal of the objection is respectfully requested.

Claim 32 has been objected to with the inquiry "What is a plant body?" Applicants respectfully submit that one skilled in the art would understand that a "plant body" simply refers to a plant. Claim 32 has been amended to express this more simply. Withdrawal of the objection is respectfully requested.

Claims 26 and 63 have been objected to with the allegation that a flower is not a tissue. No authority is presented to demonstrate that a flower is necessarily excluded from among plant tissues. Without agreeing that a "flower" cannot be a "tissue" of a plant, but simply in order to expedite prosecution, claims 26 and 63 have been canceled. Thus, the objection is moot.

Claims 46-52 are objected to as allegedly not further limiting parent claims. Claims 46-52 have been canceled. The objection is moot.

Claims 56 to 58 have been objected to, allegedly because "host" should be "host cell." Applicants respectfully point out that a host cell may be within a host body, i.e. a host can comprise one or more such host cells. Therefore, without agreeing that such an amendment is necessary, but simply in order to expedite prosecution, claims 56-58 have been amended as suggested. Claim 58 is amended to cancel subject matter, which is now recited in new dependent claim 67. Withdrawal of the objection is respectfully requested.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1-3, 5-12, 20, 22-41, 46-52 and 59-66 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 1, 5-8, 20, 22-23, 28, 33-35, 39-41 and 46-52 appear to have been rejected for reciting, in the various cited claim groupings, different features and functions of various embodiments of the claimed polynucleotides. The basis for the rejection is not clear. Applicants respectfully submit that one skilled in the art would understand the metes and bounds of the invention as claimed. For example, claim 1 recited a polynucleotide having the features described therein. Claims 5-8 depended from claim 1 and recite additional features of various embodiments of the polynucleotide of claim 1. No evidence, or even an explicit assertion, has been presented that any of the features recited in the dependent claims are incompatible or mutually exclusive with a feature recited in the parent claim. It is noted that claims 1 and 46-52 have been canceled. No prima facie basis for the rejection has been stated that can be applied to the claims as currently presented.

Claim 2 has been rejected for reciting “using” allegedly without positive method steps. Applicants respectfully submit that claim 2 recites the active process step of “cloning” and that the phrase “using as a primer a nucleotide sequence . . .” describes an element of how the cloning step is performed in a manner that would be understood by one skilled in the art. Accordingly, one skilled in the art would understand the metes and bounds of the claim.

Claims 59-61 have been rejected, because “said gene” allegedly lacks antecedent basis. Claims 59-61 have been amended to more clearly indicate the antecedent basis by replacing “said gene” with “said polynucleotide” as recited in the parent claim.

Claims 62 and 64 have been rejected for recitation of “the same property.” Without agreeing that such an amendment was necessary, claims have been amended to move the

subject matter of the clause that has been objected to so that the “plant, its progeny, or tissues of said plant or said progeny” are recited in one clause.

Claim 63 has been rejected for reciting “the plant tissue.” Claim 63 has been canceled. Thus, the rejection is moot.

For at least the foregoing reasons, withdrawal of the rejection of claims 1-3, 5-12, 20, 22-41, 46-52 and 59-66 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**Rejections under 35 U.S.C. § 112, first paragraph (Enablement)**

Claims 1-3, 5-12, 20, 22-41 and 46-52 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled for the full scope of the claimed invention. By the present amendment, claims 1 and 46-52 have been canceled. Claim 7 has been rewritten in independent form and claims 2, 3, 5, 6, 8, 9, 20 and 22-25 have been amended to depend from claim 7 in view of the cancellation of claim 1.

The rejection is respectfully traversed. Each of the pending rejected claims depend directly or indirectly from either claim 7 or 28. Claim 7, as amended, recites “An isolated polynucleotide encoding an anthocyanin acyltransferase, encoding a protein which consists of an amino acid sequence which is at least 30% homologous to any one of the amino acid sequences of SEQ ID NOs: 1 to 6, and which transfers an aromatic acyl group to flavonoid wherein said acyltransferase transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin.”

Claim 28 recites “An isolated polynucleotide encoding an anthocyanin acyltransferase, which polynucleotide encodes an amino acid sequence selected from the group consisting of the amino acid sequences as set forth in SEQ ID NOs: 1 to 6, or hybridizes with a nucleotide sequence complementary to a nucleotide sequence selected from the group consisting of the nucleotide sequences encoding the amino acid sequences as set

forth in SEQ ID NOs: 1 to 6 under the condition of 5 x SSC and 50°C or the condition of 2 x SSC and 50°C, and which anthocyanin acyltransferase transfers an aromatic acyl group to flavonoid.”

The Official Action acknowledges that the specification enables isolated polynucleotide sequences of SEQ ID NOs:1-6 encoding an anthocyanin acyltransferase, transgenic plant or plant parts expressing same and methods of expressing said sequences to alter a pigment in a plant.

Claims 7 and 28 define common structural and functional features of the members of the claimed genus of polynucleotides. The recited structural features include defined homology and/or properties of hybridization to defined sequences under defined conditions, which proscribes the structural properties of the polypeptide as one skilled in the art would clearly appreciate. Furthermore, the recited features define relationships among members of the claimed genus such that the scope of the claims corresponds to the scope of enablement in accordance with 35 U.S.C. § 112, first paragraph.

**The recited features of claims 7 and 28 correspond directly to teaching in the specification that discloses how to make any of the claimed species.** Accordingly, specification teaches one how to make and use the invention in accordance with the full scope of the claims. In the instant application, applicants teach how one skilled in the art could obtain proteins which have aromatic acyl group transfer activity, as claimed. As discussed on pages 5 and 6 of the specification, prior to the present invention all attempts to purify aromatic acyltransferases had failed. The inventors were the first to succeed in purifying this enzyme using various chromatographic techniques. The DNA obtained was sequenced, and then used as a probe. Using the teachings of the specification, for example, at page 5, line 31 - page 6, line 24. DNA encoding the amino acid sequences of SEQ ID NOs:

1-6 were thus obtained. Using the known DNA as probes, and recognizing the conserved regions (see, e.g., SEQ ID NOs: 21 and 22), additional DNA falling within the scope of the claims can be obtained, as described at the very least at pages 9-10. By using this method, one of skill in the art can isolate proteins which have aromatic acyl group transfer activity, and which have the structural properties recited in the claims.

**Furthermore, enablement of the claimed genus is demonstrated by the representative number of working examples described in the specification.** For example, in Example 6 the applicants describe cDNA of gentian origin; in Example 8, cDNA of petunia origin is disclosed; and in Example 20, cDNA of lavender origin is disclosed. The cDNA's disclosed in Examples 6, 8 and 20 were obtained using a hybridization method as described in the specification to select desired cDNA. Example 11 describes a cDNA of perilla origin and Example 12 describes a cDNA of cineraria origin. The cDNA's of both Examples 11 and 12 were obtained by using synthetic DNA primers.

One of skill in the art could obtain a protein having an aromatic acyl group transfer activity and the structural features described in the claims by applying the methods shown in the representative Examples 6, 8, 11, 12 and 20, which are described in detail in the specification, e.g., pages 5-6, page 9, line 36 - page 10, line 29.. Example 3 teaches the probe which is used in Examples 6 and 8 to obtain a protein with aromatic acyl group transfer activity. Example 20 uses the same hybridization method as that taught in Example 3, but with a different flower species (i.e., *lavandula angustifolia* as opposed to *petunia hygrida* or *gentian*). In Example 11, the applicants compared amino acid sequences from the proteins obtained in Examples 3, 6 and 8, and determined that a amino acid sequence was conserved between these proteins. They used this sequence to produce a primer which will amplify aromatic acyl transfer genes. The applicants used this primer to amplify DNA from a cDNA

library developed from perillas, and obtained a protein with aromatic acyl group transfer activity. In Example 12, the primer was also used to screen for genes in *Senecio cruentus*. Thus, the applicants have shown that primers from this conserved region can be used to isolate members of the claimed genus.

The Official Action alleges that with regard to claims that recite sequence homology, that there is no guidance of regions of the disclosed sequences that can be modified. Applicants respectfully submit that one skilled in the art would be guided by a comparison of the representative species disclosed in the specification. Such a comparison is taught in the specification and further aspects would be apparent to one skilled in the art from consideration of the representative species. Together with additional teachings throughout the specification and further in view of well understood principles of conservative sequence modifications, one skilled in the art would be capable of making and using the full scope of the claimed invention.

Enablement is not precluded by the necessity for some experimentation. Under the requirements of 35 U.S.C. § 112, first paragraph, the standard is that any experimentation needed to practice the invention must not be undue experimentation. The "key" word is undue, not experimentation. The Official Action has not established that any routine screening of candidates would be undue.

For at least the foregoing reasons, withdrawal of the rejection is proper and is respectfully requested.

**Rejections under 35 U.S.C. § 112, first paragraph (Written Description)**

Claims 1-3, 5-12, 20, 22-41 and 46-52 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not described in the specification in such a way as to reasonably



convey that the inventors had possession of the claimed invention at the time the application was filed. By the present amendment, claims 1 and 46-52 have been canceled. Claim 7 has been rewritten in independent form and claims 2, 3, 5, 6, 8, 9, 20 and 22-25 have been amended to depend from claim 7 in view of the cancellation of claim 1. The rejection is respectfully traversed.

Each of the pending rejected claims depend directly or indirectly from either claim 7 or 28. Claims 7 and 28 define common structural and functional features of the members of the claimed genus of polynucleotides. The recited structural features include defined homology and/or properties of hybridization to defined sequences under defined conditions, which proscribes the structural properties of the polypeptide as one skilled in the art would clearly appreciate.

Furthermore, contrary to allegations in the Official Action, the recited properties define structural relationships among members of the claimed genus that correspond directly with the recited functional features as demonstrated by the representative number of working examples disclosed in the specification. The Official Action quotes at length from *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) in support of the rejection. However, *Eli Lilly* does not control the result in this case, because unlike in *Eli Lilly* the present applicants have disclosed numerous complete sequences within the scope of the claimed genus. As pointed out in the *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement*, even one species may adequately support a genus. Further, "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 F.R. 1099, 1106 (2001)

The claimed genus is clearly described in accordance with the requirements of 35 U.S.C. § 112, first paragraph as shown in the Office's own training materials. The Examiner's attention is respectfully directed to the Synopsis of Application of Written Description Guidelines of the United States Patent Office at Example 9, which addresses the issue of hybridization directly. The Guidelines indicate that under facts analogous to those of the present case, claims such as 5, 6 and 28 reciting hybridization to a known sequence under defined conditions meet the written description requirements. Using the same analytical approach, it can be seen that the combination of structural and functional properties recited in claim 7 define a genus of related polynucleotides that is adequately described in accordance with the requirements of 35 U.S.C. § 112, first paragraph.

For at least the foregoing reasons, withdrawal of the rejection is proper and is respectfully requested.

#### **Rejections under 35 U.S.C. § 102**

Claims 1-3, 5-6, 9-12, 20, 22-41, 46, 48 and 51-52 have been rejected under 35 U.S.C. § 102 as allegedly anticipated by Brugliera (WO 94/03591). The Official Action alleges that Brugliera teaches a flavonoid-3-glucotransferase (3RT). The rejection is respectfully traversed.

By the present amendment, claims 1 and 46-52 have been canceled. Claim 7 has been rewritten in independent form and claims 2, 3, 5, 6, 8, 9, 20 and 22-25 have been amended to depend from claim 7 in view of the cancellation of claim 1. The Official action acknowledges that claim 7 is free from the prior art, because the prior art fails to teach or suggest a protein having 30% or greater sequence identity to SEQ ID NOS: 1-6. Therefore,

in view of the present amendment, claims 2 , 3, 5-6, 9-12, 20, 22-25 and 27 must also be free of the prior art.

Moreover, the Official Action has failed to present a prima facie case of anticipation required to support a rejection of claims 28-41 under 35 U.S.C. § 102. To anticipate a claim, every element of the claimed invention must be found in a single prior art reference.

M.P.E.P. § 2131. "The identical invention must be shown in complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1990). The Official Action fails to establish that the 3RT of Brugliera has any sequence resemblance with the polynucleotides of claims 28-41. The Official Action acknowledges that the 3RT of Brugliera has less than 30% identity with SEQ ID NO: 1-6.

The rejection of claims 28-41 thus rests upon the absence of a recitation of "wash time" in the claims. While a claim is to be given its broadest reasonable interpretation in examination, the interpretation must still be reasonable. In this case, hybridizing includes conventional conditions, such as clean equipment, that would be understood to be reasonable in the art, including wash times. When considered in this light, and in the absence of any evidence that proves that the 3RT of Brugliera could be reasonably expected to demonstrate the hybridization properties recited in claims 28-41 under the recited conditions, Applicants respectfully submit that the rejection fails to set forth the minimum showing required to support the rejection.

For at least the foregoing reasons, withdrawal of the rejection is proper and is respectfully requested.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 9, 2004

By: \_\_\_\_\_  
Christopher L. North  
Registration No. 50,433

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620